DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-655/S-006

Watson Laboratories, Inc.
Attention: Wendy DeSpain, R.A.C.
Associate, Regulatory Liaison
417 Wakara Way
Salt Lake City, Utah 84108

Dear Ms. DeSpain:

Please refer to your supplemental new drug application dated November 28, 2000, received November 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alora .

We also acknowledge receipt of your submission dated February 19, 2003 to this application. This submission constituted a complete response to our September 17, 2002, action letter.

This supplemental new drug application provides for multiple revisions to the package insert and patient package insert to include safety information from the Women's Health Initiative trial.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use of Alora as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the package insert and patient package insert submitted on February 19, 2003 to this supplemental application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-655/S-006." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call George Lyght, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel A. Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: agreed-upon labeling text

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames

11/18/03 05:10:10 PM